CANDELA

FEB - 9 2005

K043251

510(k) Summary

General Information:

The purpose of this premarket notification application is to provide notification of substantial equivalence of the Candela Family of Family of Pulsed Dye Laser Systems, which are substantially equivalent to previously marketed devices intended for the following indications
General Surgery: Photocoagulation of benign cutaneous vascular lesion and benign cutaneous lesions.
Dermatology/Plastic Surgery: For treatment of benign cutaneous vascular lesion, such as facial and leg telangiectasia, rosacea, port wine stains, hemangiomas, angioma, spider angioma, Poikiloderma of Civatte, and benign cutaneous lesions, such as warts, scars, striae and psoriasis. and the treatment of wrinkles.
Treatment of Inflammatory Acne Vulgaris
Gynecology: Photocoagulation of benign cutaneous lesion and benign vascular lesion in gynecology.
Podiatry: Treatment of benign cutaneous lesions, such as warts.

New Indication: Treatment of Benign Epidermal Pigmented Lesions

There have been no modifications in design of the Lasers in the Pulsed Dye Family of Laser Systems which were previously cleared under K001093, K021180,
K033331 and K033461.

Submitted by:	Candela Corporation 530 Boston Post Road Wayland, MA 01778-1886
Contact Person:	Lorraine Calzetta
Date prepared:	November 12, 2004
Classification:	Class II (21 CFR § 878.4810 Laser Surgical Instrument for use in General and Plastic Surgery and in Dermatology)
Common Name:	Dermatology Laser, Family of Pulsed Dye Laser Systems

Predicate Devices

Candela SPTL 1B Laser	**Candela Cbeam Pulsed Dye Laser (aka**	**Candela Vbeam Pulsed Dye Laser**	*Cynosure Apogee*	*Laserscope Aura KTP Laser*	*GentelLASE Family of laser Systems*

	Clearbeam)				
K001093	**K021180 K033331**	**K033461**	K031488	K984424 K024206	K024371

Description:

The Candela Family of Pulse Dye Laser Systems are flash-lamp excited pulsed dye medical lasers, controlled by an embedded microprocessor., to be used for the following uses in:
General Surgery: Photocoagulation of benign cutaneous vascular lesion and benign cutaneous lesions.
Dermatology/Plastic Surgery: For treatment of benign cutaneous vascular lesion, such as facial and leg telangiectasia, rosacea, port wine stains, hemangiomas, angioma, spider angioma, Poikiloderma of Civatte, and benign cutaneous lesions, such as warts, scars, striae and psoriasis. and the treatment of wrinkles.
Treatment of Inflammatory Acne Vulgaris
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New Indication: Treatment of Benign Epidermal Pigmented Lesions

The Lasers may be used with the Candela Dynamic Cooling Device, which provides a short burst of cryogen spray prior to firing the laser pulse. The laser output energy is delivered via an optical fiber to a hand piece. The cryogen, which is housed within the laser enclosure, is delivered via a hose to a nozzle located in the hand piece .The Candela Family of Pulsed Dye Laser Systems are equipped with safety interlock systems to protect patients and operators. Users of the device make selections from an onboard control panel to regulate operation during treatment.

Testing:

As a laser product, the Family of Pulsed Dye Laser Systems are required to conform and do conform to the Laser Performance Standard (21 CFR 1040). In addition the lasers conform to the Harmonized Standard EN 60601 1-2, Part 2 established by and required by the European Community.

Summary of Substantial Equivalence:

The Candela Family of Pulsed Dye Laser Systems is equivalent in key design aspects, functional features and indications for use as the predicate devices for the treatment of epidermal pigmented lesions.

On the basis of similarities in functional features, method of operation, and intended uses, Candela Corporation believes that the Candela Family of Pulsed Dye Laser Systems are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 9 2005

Ms. Lorraine Calzetta Patrovic
Manager, Regulatory Affairs
Candela Corporation
530 Boston Post Road
Wayland, Massachusetts 01778

Re: K043251
Trade/Device Name: Candela Family of Pulsed Dye Laser Systems
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: November 12, 2004
Received: November 23, 2004

Dear Ms. Patrovic:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

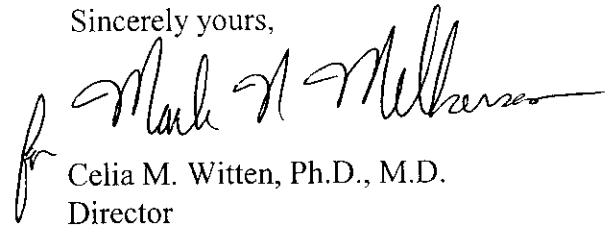
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K043251

Device Name: Candela Family of Pulsed Dye Laser Systems

Indications For Use:

The Candela Family of Pulse Dye Laser Systems is indicated for the following uses in:

General Surgery: Photocoagulation of benign cutaneous vascular lesion and benign cutaneous lesions.

Dermatology/Plastic Surgery: For treatment of benign cutaneous vascular lesion, such as facial and leg telangiectasia, rosacea, port wine stains, hemangiomas, angioma, spider angioma, Poikiloderma of Civatte, and benign cutaneous lesions, such as warts, scars, striae and psoriasis. and the treatment of wrinkles.

Treatment of Inflammatory Acne Vulgaris

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Podiatry: Treatment of benign cutaneous lesions, such as warts.

New Indication: Treatment of Benign Epidermal Pigmented Lesions

Prescription Use _X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K043251